1. Purpose

This supplement requirement is specific requirements for medical laboratory compliance with ISO 15189, ISO 15189 with ISO 15190 and/or with ISO 22870.

2. Application

This supplement requirements are specified the requirements that the medical laboratory shall establish the policy and procedure to ensure that the medical laboratory comply with this supplement requirement and international standard for medical laboratory.

3. References

3.1 ISO 15189: 2012 Medical laboratories- Requirements for quality and competence.

☞ 3.2 ILAC-G26:11/2018 Guidance for the Implementation of a Medical Accreditation Scheme.

4. Definition and abbreviation

Medical Laboratory or Clinical Laboratory means laboratory for the biological, microbiological, immunological, chemical, immune-hematological, hematological, biophysical, ☞ cytological, pathological or other examination of materials derived from the human body and/ or direct testing on the human body for the purpose of providing information for the diagnosis, prevention and treatment and/or monitoring of diseases in (or assessment of the health of) human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

Medical laboratories may be stand-alone institutions or part of a larger organization such as a hospital or clinic. Impartiality needs to be established in the absence of any commercial financial or other pressures that may affect technical judgments. Potential conflicts of interest due to financial or referral arrangements need to be avoided.

Facilities that only collect/prepare/transport samples, or act as a mailing or distribution center are not considered as stand-alone medical laboratories, although they may be part of a larger laboratory network or system.

The management system requirements in ISO 15189 are written in a language relevant to medical laboratory operations and meet the principles of ISO 9001. The technical requirements are a comprehensive set of elements essential to consistently deliver valid test results.

5. Associated Documents

5.1 N 07 15 003 Policy and requirements for proficiency testing, interlaboratory comparison/ laboratory's performance assessment in test

6. Procedures

Supplement Requirements

6.1 Personnel

6.1.1 The responsible persons in medical laboratory are doctors, medical technologists, scientists, medical scientists, technicians, assistants, or other staff who are trained and evaluated of competence, where necessary and appropriate.

6.1.2 The laboratory staff shall be evaluated of knowledge/ competence in time scale to fulfill the qualification and job descriptions.

6.1.3 Part time and overtime staff of the laboratory shall receive the same training, ongoing education and professional development as fulltime staff.

6.1.4 The laboratory should be sufficiently independent so that no one outside of the laboratory can change examination results

6.2 Accommodation and environmental conditions

6.2.1 The laboratory shall have adequate space and suitable environment to ensure that its work can be performed without cross contamination or compromising the quality of work. Besides that, it shall be considered of safety of personnel, patient, employees and visitors.

6.2.2 The molecular biology laboratory works on nucleic acid amplifications, and/or analysis of high risk organisms such as mycobacterium, SARS, etc., shall be separated and has suitable environmental condition.

6.2.3 For maintenance of safety environment in the laboratory, ISO 15190: Medical laboratories - Requirements for safety is recommended standard to be implemented.

6.3 Laboratory equipment, reagents, and consumables

6.3.1 The laboratory shall be furnished with all items of equipment, instrument, consumables, reference materials and reagents required for the provision of services. Purchased items shall consistently meet the laboratory's quality requirements. There shall be procedures for handling, storage, maintenance and a regularly monitoring program.

6.3.2 The laboratory are responsible for ensuring that manufacturers' performance claims are met, and that calibration services provided by manufactures meet needs. The fitness to the intended use should be ensured.

6.3.3 When laboratories use different equipment or examination methods, the comparability of these different examination systems needs to be assured.

6.3.4 The laboratory shall have firefighting equipment, chemical and hazardous materials protection equipment and first aid kit in case of accident occur, where necessary and appropriate.

6.4 Pre-examination processes

6.4.1 The laboratory shall prepare a procedure for customers to follow. This procedure shall include test of analysis, patient preparation, sample collection, sample container, handling of sample, completion of request from, turnaround time, criteria for acceptance or rejection of primary samples, safety of collection and handling of samples and receiving/sending of test report.

6.4.2 The laboratory shall hand over such a document in clause (6.4.1) to the customers. The handling or receiving records shall be maintained by the laboratory.

6.4.3 The laboratory staff may not collect all or any samples for examination. However, laboratories are still responsible for ensuring that samples received are not compromised.

6.5 Examination processes

6.5.1 The laboratory shall have all examination procedures which have been accredited according to ISO 15189. Laboratories shall validate examination procedures when using non-standard methods, laboratory designed or developed methods, standard methods used outside their intended scope and validated methods subsequently modified.

6.5.2 Examination procedures shall indicate reference used by laboratory and it shall be available where necessary.

6.5.3 Special care shall clearly specify in the examination procedure, if testing with the high-risk organisms or chemical or hazardous materials.

6.6 Ensuring quality of examination results

6.6.1 The laboratory shall have the internal quality control of all examination procedures which have been accredited according to ISO 15189. The results of IQC shall be analyzed and evaluated.

6.6.2 Laboratory shall follow the ISO 15189 clause 5.6.4, 5.6.5 and the BLQS notice on Proficiency Testing and Interlaboratory comparison (N 07 15 003).

6.7 Post-examination processes

The laboratory shall have a procedure for storage and safe disposal of samples no longer required for examination. Safety in laboratory environment and general public shall be considered by laboratory.

6.8 Reporting of results

6.8.1 The laboratory shall set the turnaround time and inform to the customer.

6.8.2 Results shall be legible, without mistake in transcription and reported to persons authorized to receive and use medical information.

6.8.3 The laboratory shall not give the test report directly to the patient or the patient's relative if report result can affect violent emotion to the patient. The result of HIV, DNA identification or other results shall be forward to authorized person as indicated in the requirements of professional association standards or a regulation. However, the laboratory shall have a procedure for sending report to the clinician or authorized person as appropriate.

6.9 Additional requirement for ISO 15189: 2012

6.9.1 Preventive action

Preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).

6.9.2 Continual improvement

Improvement activities shall be directed at areas of highest priority based on risk assessments.

6.9.3 Evaluation and audits

6.9.3.1 The laboratory shall plan and implement the evaluation and internal audit processes needed to:

a) Demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;

b) Ensure conformity to the quality management system;

c) Continually improve the effectiveness of the quality management system.

6.9.3.2 The results of evaluation and improvement activities shall be included in the input to the management review. Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.

6.9.3.3 Assessment of user feedback and Staff suggestions

The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.

Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.

6.9.3.4 Risk management

The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, personnel safety and process effectiveness and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

6.9.3.5 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

6.9.3.6 Reviews by external organizations

When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken.

6.9.4 Management review

Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

6.9.4.1 Review input

The input to management review shall include information from the results of evaluations of at least the following ISO 15189: 2012 clause 4.15.2 a-o)

6.9.4.2 Review activities

The review shall analyze the input information for causes of nonconformities, trends and patterns that indicate process problems. This review shall include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, also be objectively evaluated.

6.9.4.3 Review output

The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:

a) improvement of the effectiveness of the quality management system and its processes;

b) improvement of services to users;

c) resource needs.

6.9.5 Release of results

The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.

6.9.5.1 If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:

a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff. Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values;

b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;

c) there is a process for indicating the presence of sample interferences (e.g. hemolysis, icterus, lipemia) that may alter the results of the examination;

d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;

e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;

f) there is a process for rapid suspension of automated selection and reporting.

6.9.5.2 Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

b) the user is made aware of the revision;

c) the revised record shows the time and date of the change and the name of the person responsible for the change;

d) the original report entries remain in the record when revisions are made.

Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised.

When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.

6.9.6 Laboratory information management

The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.

The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

6.9.6.1 Authorities and responsibilities

The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:

a) access patient data and information;

b) enter patient data and examination results;

c) change patient data or examination results;

d) authorize the release of examination results and reports.

6.9.6.2 Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation, validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory

instrumentation, hospital patient administration systems and systems in primary care;

b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;

c) protected from unauthorized access;

d) safeguarded against tampering or loss;

e) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;

g) in compliance with national or international requirements regarding data protection.

The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service.

When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

6.10 Classification of Medical Testing by Utilization

Medical tests can be classified by what the test result will be used for, mainly including usage for diagnosis, screening or evaluation, as separately detailed below

6.10.1 Diagnostic

A diagnostic test is a procedure performed to confirm, or determine the presence of disease in an individual suspected of having the disease, usually following the report of symptoms, or based on the results of other medical tests. Such tests include:

- Measuring the blood sugar in a person suspected of having diabetes mellitus, after periods of increased urination.
- Taking a complete blood count of an individual experiencing a high fever, to check for a bacterial infection
- Monitoring electrocardiogram readings on a patient suffering chest pain, to diagnose or determine any heart irregularities

6.10.2 Screening

A screening test is a medical test used to detect or predict the presence of disease in individuals at risk for disease within a defined group, such as a population, family, or workforce. Screenings may be performed to monitor disease prevalence, manage epidemiology, aid in prevention, or strictly for statistical purposes. Screening test gives preliminary result of which always needs confirmation. Diagnostic test always be used for screening purposes.

Examples of screenings include measuring the level of TSH in the blood of a newborn infant as part of newborn screening for congenital hypothyroidism, checking for Lung cancer in non-smoking individuals who are exposed to second-hand smoke in an unregulated working environment, and Pap smear screening for prevention or early detection of cervical cancer.

6.10.3 Monitoring

Some medical tests are used to monitor the progress of, or response to medical treatment. Such tests may be used as surrogate markers for diseases progression and monitoring the treatment of the patients e.g. cancer markers CA 19-9, CEA, CA 125, CD4/CD8, viral load.

6.10.4 Supplemental or Confirmatory

Some medical tests are used to obtain more information after diagnostic or screening tests are preformed e.g. Anti-HIV confirmation by using 3 combinations of screening tests. Some tests may be called special tests, if they provide special data or using special techniques.

6.10.5 Investigational

Some tests are under developing or are not passed clinical evaluation in the field trials. Such tests may be used for other purposes than diagnosis.

The medical laboratories shall indicate the purposes of the tests according to Classification of Medical Testing by utilization, together with evidences e.g. pack inserts of the reagents, in their accreditation profiles, as described in the application forms prior an initial accreditation. For accredited laboratories, the same practices are required in the next accreditation visits e.g. on-site surveillances and reassessments.

The laboratory shall submit ISO 15190 checklist (Form no.10) together with the required documents for the assessment.

Expire date of ISO 15190 accreditation certification is the same date of expiration date of ISO 15189 accreditation certification.

7. Data record and used document -

☞ **8. History of change**

Revision	Document Changes	Prepared / Revised by	Date Issued
00	Initial document	-	-
07	Change detail in Supplement requirement	Natamol Tianmanee	23 Sep 2014
08	- Change format and detail in Procedures (clause 6) - Add clause 7 and 8	Nattakarn Laieddee	10 Nov 2017
09	- Update No. 3.2 ILAC-G26:11/2018 - Add detail No. 4.Definition and abbreviation - Add detail of 6.5.1 and 6.9.3.4	Nattakarn Laieddee	

Appendix 1

Controlled copy list

1.	Director of Bureau of Laboratory Quality Standards	Code No. 07 00
2.	Head of Laboratory Accreditation Section 1	Code No. 07 03
3.	Head of Laboratory Accreditation Section 2	Code No. 07 04
4.	Quality Manager	Code No. QM 07
5.	Ms. Nattakarn Laieddee	